

K960311

APR 18 1996

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Hollister Incorporated  
Continued Pressure Biofeedback Device

## **Section VII**

### **Safety and Effectiveness Summary**

Hollister Incorporated represents that the proposed product is safe and effective for its intended use. A safety and effectiveness summary follows.

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Contimed Pressure Biofeedback Device

**Safety and Effectiveness Summary**

**1. Submitter's name, Address and Contact Person**

Submitter

Hollister Incorporated  
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Contact Person

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Date Summary Prepared - January 18, 1996

**2. Name of Device:**

Hollister Contimed Pressure Biofeedback device

**3. Name of Predicate Device(s)**

- Perineometer as described in 21 CFR 884.1425
- InCare Contimed II Pressure Biofeedback device, K891774 (8/23/89).

**4. Description of Device**

The Contimed Pressure Biofeedback device is intended to help strengthen pelvic floor muscles in the treatment of urinary incontinence. The Contimed Pressure Biofeedback device is a battery powered machine which registers the force with which a patient contracts their pelvic floor muscles. The force is measured by using an anatomically shaped, inflatable pressure probe that is connected to the Contimed device. The latex probe (anal or vaginal) is inflated with air by using a syringe and is introduced into either the vagina or anus. The voluntary muscle contractions of the exercises compress the air inside the probe and register a reading on the display panel of the Contimed device. The visual display of contraction force gives the patient the ability to see and hear progress in the exercise session. The Contimed has a vertical column of lights. The number of the lights illuminated increases or decreases with an increase or decrease of contraction force. To reinforce the effect of the visual signal there is also an audible signal that can be turned on or off. The intensity of the tone increases or decreases in intensity depending on the contraction's force. Over time the exercise program will help the patient to improve the ability to control the pelvic floor muscles.

Three different duty cycles are preset to allow the caregiver the ability to choose a program that will help to strengthen the pelvic floor muscles. They can be set by using the slide switch on the control panel of the device. Three sensitivity levels are available to accommodate different contraction strengths of the pelvic floor muscles. They can be set by using the slide switch on the control panel of the device, there is also a slide switch for zero adjustment. The chart below describes the parameters that are preset into the Contimed Pressure Biofeedback device of both.

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<b>Work/Rest 3 Cycles (seconds)</b>		<b>3 sensitivity levels expressed in millimeters of mercury</b>
<u>Work</u>	<u>Rest</u>	
5s	10s	0- 25mm Hg
10s	20s	0- 50mm Hg
30s	60s	0-100mm Hg

**5. Statement of Intended Use**

The Contimed Pressure Biofeedback device is intended to provide pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles in the treatment of urinary incontinence.

**6. Statement of Technological Characteristics of the Device**

a. The proposed Contimed device and the predicate device InCare Contimed II use piezoresistive (strain gauge) pressure sensors. The piezoresistive elements are connected in a Wheatstone bridge configuration. The pressure sensor used in the predicate device InCare Contimed II has internal temperature compensation and internal zeroing adjustment. The pressure sensor used in the proposed Contimed device does not have those two functions internal to its construction. These differences between the proposed and predicate device are not significant issues because: 1. The temperature range in which the devices are used is narrow (e.g. room temperature) and 2. The transducer zeroing is not a critical issue because these products are used for relative measurements. That is, any offsets and resting pressures are "zeroed out" by patient (using the zero button or slide potentiometer) when the exercise is started. However, the proposed Contimed device does have a calibration potentiometer on the circuit board which is used to adjust the pressure sensing circuitry during the manufacturing process.

b.

**Comparison of the Similarities and Differences of InCare Contimed Pressure Biofeedback device and InCare Contimed II Biofeedback device, K891774 (8/23/89)**

<b>Characteristic</b>	<b>Proposed device Contimed Pressure Biofeedback device</b>	<b>Predicate device Contimed II Biofeedback device K891774 (08/23/89)</b>
Intended Use	Treatment of female urinary incontinence	Treatment of female urinary incontinence
Power Source	9 Volt alkaline battery	9 Volt alkaline battery
Sensitivity levels	0-25mm Hg 0-50mm Hg 0-100mm Hg	0-25cm H <sub>2</sub> O 0-50cm H <sub>2</sub> O 0-100cm H <sub>2</sub> O

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Work Period (sec)	5, 10, 30 (preset)	5, 10, 30 (preset) or option of care-giver to set the patient's individual therapeutic needs.
Rest Period (sec)	10, 20, 60 (preset)	10, 20, 60 (preset) or option of care-giver to set the patient's individual therapeutic needs.
Session Length (min)	Labeling recommends no longer than 30 minutes	Labeling recommends no longer than 30 minutes, automatic shut-off after 15 minutes.
Recommended Probes	InCare Anal probe, Stock 9586 (K891774) InCare Vaginal probe, Stock 9585 (K891774)	InCare Anal probe, Stock 9586 (K891774) InCare Vaginal probe, Stock 9585 (K891774)
Indication of Contraction Force (Feedback Provided to User)	1. Optional audio intensity increases or decreases with increase or decrease in contraction force. 2. Visual display - vertical column of lights. Number of lights illuminated increases or decreases with increase or decrease in contraction force.	1. Optional audio intensity increases or decreases with increase or decrease in contraction force. 2. Visual display - 30° angle of horizontal lights. Number of lights illuminated increases or decreases with increase or decrease in contraction force.
Machine Controls	Slide switch controls.	Membrane switch controls.
Patient data	Does not save patient data.	Has built in 30 day diary to monitor patient progress.
Pressure Zeroing Function	Slide potentiometer.	Membrane switch. (single press)
Transducer Type	Piezoresistive (strain gauge)	Piezoresistive (strain gauge), internal temperature with compensation and zeroing adjustment

## 7. Conclusion

Based upon the information presented above it is concluded that the proposed Contimed Pressure Biofeedback device is safe and effective for its intended use and is substantially equivalent to the predicate device.